



29 January 2019

**OMEGA DIAGNOSTICS GROUP PLC
("Omega" or the "Company" or the "Group")**

**VISITECT® CD4 Advanced Disease test update
Successful manufacture of three validation batches**

Omega (AIM: ODX), the medical diagnostics company focused on allergy, food intolerance and infectious disease, announces that it has successfully manufactured three validation batches of its VISITECT® CD4 Advanced Disease test.

Finished devices were tested in India, Zimbabwe and the UK and results demonstrate that all three batches performed in line with the Company's design goal parameters. These validation batches prove we can manufacture at scale and are a requirement for obtaining a CE Mark.

As previously communicated, we continue to make good progress and expect to complete internal verification work and external performance evaluation of venous whole blood samples during February.

We have also made progress with planned external performance evaluations of finger prick samples as follows;

- Zimbabwe – performance evaluation on finger prick blood commenced at the end of December 2018 and is estimated to be 50% complete
- India – ethics approval has recently been granted with the evaluation expected to commence in February 2019

We also note the interest from organisations such as Unitaid that have recently launched an initiative to avert preventable deaths from advanced HIV disease.¹

Colin King, Chief Executive of the Group, commented: *"I am pleased to announce that we continue to deliver against our timeline for the VISITECT® CD4 Advanced Disease test. I am also encouraged by the outlook for this product as key stakeholders continue to engage with us about the sizeable opportunity once we bring the test to market."*

The information communicated in this announcement is inside information for the purposes of Article 7 of EU Regulation 596/2014.

¹<https://unitaid.org/news-blog/unitaid-launches-initiative-to-avert-deaths-from-advanced-hiv/#en>

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